

Efforts by the U.S. Geological Survey for the expansion and extension of the U.S. label for use of oxytetracycline in public aquaculture

Aquaculture America 2003
Louisville, Kentucky

Goals of the IAFWA project

To expand a label or obtain a label for use in public aquaculture for:

AQUI-S

Chloramine-T

Florfenicol

Formalin

Hydrogen Peroxide

Oxytetracycline



Approved uses for oxytetracycline

Feed additive to control certain diseases
in salmonids and catfish

To mark salmonid skeletal tissue

To control gaffkemia in lobster



Envisioned Label Claim

Species: All freshwater-reared finfish

Indication: Control mortality associated with hemorrhagic septicemia (*A. hydrophila*), pseudomonas disease, and systemic columnaris

Dosage Regimen: 2.5 to 3.75 g/ 100 lbs fish



Technical sections

Efficacy - cool and warm water fish

Environmental safety

Target animal safety - cool and warm water fish

Human food safety

Efficacy of Oxytetracycline

Supplementary efficacy
data from call-in submitted
to CVM Jan. 1999

Analytical support for dose
verification in pivotal trials

Several attempts for pivotal trials at
Iowa hatcheries were unsuccessful



Let's move on to...

Efficacy - cool and warm water fish

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Environmental safety of Oxytetracycline

Literature review of fate and effects
previous EAs for OTC

Fate model after discharge from hatcheries

Toxicity data from literature

Validation by hatchery study planned

Let's move on to...

Efficacy - cool and warm water fish

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Target animal safety of Oxytetracycline

Species:

cool water: walleye, yellow perch

warm water: hybrid striped bass

**1, 3, and 5X the maximum label dose for
10 days except 20 days in walleye**



Target animal safety of Oxytetracycline

Behavioral measures

Histopathology

Submitted Feb. 2003



Let's move on to...

Efficacy - cool and warm water fish

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Human food safety

Human food safety of Oxytetracycline

Method for the marker residue

Marker residue depletion

Antimicrobial resistance



Human food safety of Oxytetracycline

Official method a microbial inhibition assay

Specific chemical method preferred

Bridged microbial assay to HPLC method

Human food safety of Oxytetracycline

Method for the marker residue

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Antimicrobial resistance



Human food safety of Oxytetracycline

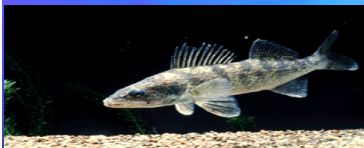
Species of Fish	Dosage (mg/kg fish/day)	Withdrawal (days)
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Coho Salmon

88

3



Walleye

89

0



Northern pike

71

0

Northern pike

94

0

Human food safety of Oxytetracycline

UMESC requested calculation of
withdrawal time for all sizes of salmonids

CVM responded with a 21 d withdrawal
time (May 2002)

Human food safety of Oxytetracycline

Method for the marker residue

Marker residue depletion

Antimicrobial resistance

Human food safety of Oxytetracycline

Antibacterial resistance related to human food safety must be addressed for new uses

Argument can be made that new uses result in small percentage increase

Accepted for OTC marking

Total use of OTC 1470 tons in 1999

Letter and data submitted to CVM in Oct. 2002

Summary of our contributions to Oxytetracycline technical sections

Environmental safety – In progress, nearly complete

Human food safety – All submissions made

Efficacy – supplementary data accepted

Target animal safety – Recently submitted

What remains...

Environmental safety – Field validation

Human food safety - Should satisfy all FW species label

Efficacy – Pivotal trials needed for additional species and diseases

Target animal safety - Should satisfy all FW species label